



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,391	01/07/2002	Jamey D. Marth	19452A-000320US	7913
20350	7590	08/29/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,391	MARTH ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 6-7-06.

Claims 36-49 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-7-06 has been entered.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 36, 38-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of systemic C2 GlcNAc T^A or conditional C2 GlcNAc T^F homozygous mice using Cre-loxP recombination, whereby a deficiency of C2 GlcNAc transferase activity and a deficiency of core 2 O-glycan synthesis were observed in isolated null mouse splenocytes, and being enabling for

Art Unit: 1635

core 2 GlcNAc substrate analogs, does not reasonably provide enablement for methods of inhibiting inflammatory responses in a mammal, or for methods of modulating binding of a first myeloid cell to a second myeloid cell or to an endothelial cell in an organism comprising the administration of compounds that are analogs of core 2 GlcNAc transferase acceptor substrates in an organism.

Applicant's arguments filed 6-7-06 have been fully considered but they are not fully persuasive. Applicant argues that glycosyltransferases are capable of targeting the appropriate subcellular organelle of cells in the bloodstream to exert a physiological effect in vivo. Applicant cites Camenish et al, Morin et al and Kijima-Suda et al as enabling references for such subcellular organelle delivery. Applicants are correct that these cited references provide evidence of the ability of substrate analogs of various glycosyl transferases (e.g. defined, small molecules) to reach the desired target and inhibit to target transferase. But, contrary to Applicant's assertions, the ability of these small substrate analogs to provide for physiological effects is neither correlative nor representative of the ability of substrate acceptor analogs of core 2 GlcNAc transferase to reach the target cell subcellular organelles in the required quantity to provide inhibition and treatment effects in an organism. The instant disclosure and art do not adequately describe a representative number of species of the genus embraced by *substrate acceptor analogs of core 2 GlcNAc transferase* which provide for the function claimed, of providing treatment effects in an organism. Thus the instant disclosure is not enabled for the full scope claimed, comprising methods of inhibiting an inflammatory response in a mammal, methods of inhibiting binding of a first myeloid cell to either an

Art Unit: 1635

endothelial cell or to a second myeloid cell, and methods of treating inflammatory diseases in a subject comprising the administration *substrate acceptor analogs of core 2 GlcNAc transferase*. For these reasons, the rejection for lacking enablement over the scope claimed, and drawn to the genus comprising substrate acceptor analogs of core 2 GlcNAc transferase that inhibit inflammation in a mammal upon administration by any means, is maintained.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 39-43, 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Morin et al.

Morin et al (Cancer Res., Vol. 43, page 4, 1983) teach methods of inhibiting an inflammatory response in a mammal and methods of inhibiting binding of a first myeloid cell to either an endothelial cell or to a second myeloid cell, comprising the administration (including parenteral administration) of a core 2 GlcNAc transferase substrate to the mammal (see the abstract on p. 4).

Claims 36, 39-43, 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Kyung Book Univ.

Kyung Book Univ. (Kyung Book Univ., Enterprising form/report No. 911-0403-007-2, 1991) teaches methods of inhibiting an inflammatory response in a mammal, methods of inhibiting binding of a first myeloid cell to either an endothelial cell or to a second myeloid cell, and methods of treating inflammatory diseases in a subject comprising the administration (including parenteral administration) of a core 2 GlcNAc transferase substrate to the mammal (see the abstract on p. 1).

Claims 36, 37, 39-43, 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by DeClercq.

DeClercq et al (Biochem. J., Vol. 205, pages 1-13, 1982) teaches methods of inhibiting an inflammatory response in a mammal, methods of inhibiting binding of a first myeloid cell to either an endothelial cell or to a second myeloid cell, and methods of treating inflammatory diseases in a subject comprising the administration (including parenteral administration) of a core 2 GlcNAc transferase substrate to the mammal (see the pages 1 and 11).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

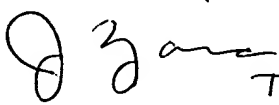
Art Unit: 1635

(December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
8-20-06


JANE ZARA, PH.D.
PRIMARY EXAMINER